



**Good Shepherd / Lehigh University**

**Collaborative Research Intake Form**

*This form must be completed and sent to* [*inirb@lehigh.edu*](mailto:inirb@lehigh.edu) *and* [*research@gsrh.org*](mailto:research@gsrh.org) *prior to IRB submission. This form will be reviewed by the GSR-LU Research Committee, and PIs will be invited to attend the meeting. A representative from the committee will communicate all determinations and next steps to the GSR and LU PIs.*

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| **Good Shepherd Research Personnel** | |
| **Good Shepherd P.I.’s Name:** | |
| **List all Good Shepherd personnel who will be** [**engaged**](https://research.lehigh.edu/policies-guidance-forms/guidance-human-subjects-research-engagement) **in human subjects research**: | |
| **Name(s):** | **Role(s):** |
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| **Lehigh University Research Personnel** | |
| **Lehigh P.I.’s Name:** | |
| **List all Lehigh personnel who will be** [**engaged**](https://research.lehigh.edu/policies-guidance-forms/guidance-human-subjects-research-engagement) **in human subjects research**: | |
| **Name(s):** | **Faculty, staff, grad student, undergrad student?:** |
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| **Study Information** |
| 1. **Title of the study:**  |  | | --- | |  |  1. **Please indicate the source(s) of funding associated with this research:**   **External - federal (specify agencies:**      **)**  **External - other (list sponsor:**      **)**  **Internal / institutional**  **Other (please specify:**      **)**   1. **Anticipated start date of this research:** 2. **List all data collection sites:**  |  | | --- | |  |  1. **Briefly summarize (1-2 paragraphs) the research study:**  |  | | --- | |  |  1. **Summarize the role of Good Shepherd personnel. Describe the specific human subjects research activities in which Good Shepherd personnel will be involved (e.g., interaction or intervention with participants, obtaining informed consent, obtaining identifiable data and/or biospecimens):**  |  | | --- | |  |  1. **Summarize the role of Lehigh personnel. Describe the specific human subjects research activities in which Lehigh personnel will be involved (e.g., interaction or intervention with participants, obtaining informed consent, obtaining identifiable data and/or biospecimens):**  |  | | --- | |  |  1. **Indicate which of the following participant populations will be included. Select all that apply:   Children (<18 years old)**   **Adults (>18 years old)**  **Non-English Speakers  Cognitively Impaired Persons  Incarcerated Persons**  **Pregnant Persons**   1. **Are the results of this study expected to apply only to GSR patients/programs, or will these results be generalizable to other settings/patients/medical professionals/knowledge?**  **Specific to GSR only  Will contribute to generalizable knowledge** 2. **Does this study involve the collection of identifiable data and/or biospecimens?   Yes  No  If yes, please describe whether data will be de-identified after data collection, and please describe the de-identification process.**  |  | | --- | |  |      1. **Does this study involve the use of** [**Protected Health Information**](https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html#what) **(PHI) from patient medical records?** (Note: data is not considered PHI when provided directly by the participant to the researcher.)   **Yes; PHI will be collected prospectively**  **Yes**; **PHI will be collected retrospectively**  **No PHI will be used**   1. **Does this study involve data collection through interaction and/or invention with patients?   Yes; data will be collected from GSR patients  Yes**; **data will be collected from patients outside of GSR (specify location:** **)**   **No; data will not be collected from patients.**   1. **Is this study a** [**Clinical Trial**](https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition#nih-definition-of-a-clinical-trial)**?**   *A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.*  **Yes**  **No**  **Not sure. Describe:**     1. **Does this study involve a** [**Medical Device, as defined by the FDA**](https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device)**?**   **Yes**  **No  Not sure. Describe:**   1. **Does this study involve a** [**Drug, as defined by the FDA**](https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#D)**?   Yes**   **No  Not sure. Describe:** |

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| **Conflict of Interest (Lehigh faculty and staff only)**  [*Significant Financial Interests*](https://research.lehigh.edu/node/478#significant-financial-interest)[*related*](https://research.lehigh.edu/research-integrity/financial-conflicts-interest-research-and-sponsored-programs/fcoi-glossary#related) *to research must be disclosed in accordance with the* [*Lehigh University policy on Conflicts of Interest Related to Research and Sponsored Programs.*](https://research.lehigh.edu/policies-guidance-forms/policy-financial-conflicts-interest-related-research-and-sponsored-programs) |
| **Do any project personnel have** [**Significant Financial Interests**](https://research.lehigh.edu/node/478#significant-financial-interest)[**Related**](https://research.lehigh.edu/research-integrity/financial-conflicts-interest-research-and-sponsored-programs/fcoi-glossary#related) **to the research described in this application that require disclosure pursuant to the** [**Lehigh University policy on Conflicts of Interest Related to Research and Sponsored Programs**](https://research.lehigh.edu/policies-guidance-forms/policy-financial-conflicts-interest-related-research-and-sponsored-programs)**?**  **No**  **Yes**:  Name of Project Personnel with Significant Financial Interests to disclose**:**    Has the disclosure already been submitted via the [Lehigh Integrated Research Administration (LIRA)](https://liracoi.huronresearchsuite.com/COI) system?  **No**  **Yes** |
| **Conflict of Interest & Ethical Behavior (Good Shepherd Associates Only)**  *All associates must abide by Good Shepherd Rehabilitation’s policies on Conflict of Interest (HR 02.18) and Code of Ethical and Professional Behavior (GOV.04).* |
| **Do any project personnel have any conflicts of interest to disclose related to the research described in this application?**  **No**  **Yes**:  Name of Project Personnel with Conflict of Interests to disclose**:**  Has the disclosure already been submitted to the Good Shepherd Research Committee?  **No**  **Yes** |